October 2007

Washington State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Dept. of Health, PO Box 47863, Olympia, WA, 98504-7863
https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm

No. 946 Pharmacy Inspections – Tips and Expectations

The Washington State Board of Pharmacy conducts pharmacy inspections to assess practice standards. This provides pharmacists with a professional and impartial review. Investigators strive to determine what is done correctly, in addition to identifying areas of concern. Inspections also present an opportunity for investigators to answer questions, share best practices, and convey information for the Board.

The most common deficiency noted during recent inspections is failure to maintain chronic medical condition information that may affect drug utilization. The second most common fault relates to the proper labeling of medications. Proper labeling includes the use of proper or accurate expiration dates.

Is it important to know that a patient suffers from diabetes or asthma before filling a prescription for a beta-blocker? Is it acceptable to assign a default expiration date of one year to all medications dispensed, regardless of stock container dating? The answers are apparent and have a direct link to patient safety.

The Board has directed its investigators to continue to emphasize the importance of collecting chronic condition information. Collecting this data, accurate labeling, and appropriate counseling will help ensure patient well-being.

No. 947 Continuing Education Units

The Washington State Board of Pharmacy encourages pharmacists to enhance their knowledge by pursuing advanced degrees and certifications in pharmacy practices. The following programs require extensive preparation. As a result, the Board has approved them for the indicated amount of continuing education units (CEU). The applicant must take and pass the certification examination. Credit will only be granted for the year that the credential is first earned. It will not be granted for renewal of these certifications.

1.5 CEUs or 15 credit hours

- *Board Certified Pharmacotherapy Specialist* administered by the American College of Clinical Pharmacy
- *Board Certified Psychiatric Pharmacist* administered by the American Society of Health-System Pharmacists (ASHP)
- *Board Certified Oncology Pharmacist* administered by ASHP
- *Certified Diabetes Educator* administered by the National Certification Board for Diabetes Educators
- *Certified Geriatric Pharmacist* administered by the American Society of Consultant Pharmacists

0.9 CEUs or 9 credit hours

- *Pharmacist Self-Assessment Mechanism*® administered by the National Association of Boards of Pharmacy®

Continuing education hours earned in excess of the hours required for a reporting period cannot be carried forward to a future reporting period.

No. 948 Prescription Opioids Fuel Sharp Rise in Poisoning Deaths

A jump in overdose deaths from the use of prescription pain killers has created what many medical officials are describing as a poisoning epidemic. There were 923 poisoning deaths in Washington State in 2005.

Both in Washington State and nationally, poisoning death rates have increased dramatically since 1980. In Washington, males ages 35 to 54 had the highest death rates. More than 90% of poisoning deaths are drug overdoses, most involving multiple drugs. Nationally and in Washington, prescription opiate overdose deaths have fueled the rise in poisoning deaths.

The rise in deaths mirrors an increase in the volume of opiates prescribed. From 1997 to 2004, sales of methadone and oxycodone increased 974% and 580%, respectively. Only methadone dispensed through pharmacies and hospitals is included, not methadone dispensed in methadone maintenance treatment programs. During this time, overdose deaths that involved methadone increased rapidly.

The shift in opiate prescribing began at the end of the 1990s when various entities in Washington State recognized the important use of opioids for chronic non-cancer pain. These new policies reflected a major shift in thinking. Some evidence

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit *www.ismp.org* and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

♦ inadequate labeling for safe use;
♦ inappropriate packaging and, therefore, uncertain product integrity;
♦ possible previous withdrawal from the US market for safety or efficacy reasons;
♦ drug-specific risks requiring initial screening and/or periodic patient monitoring;
♦ potential harm or abuse, such as with the use of controlled substances; and
♦ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments.*

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html.*

More information is available on the FDA Unapproved Drugs Web site at *www.fda.gov/cder/drug/unapproved_drugs/default.htm.*

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suggested patients were suffering from under treatment. Addiction from chronic opiate use was, at the time, thought to be a relatively low risk.

To date, interventions to change behaviors and risk factors linked to the epidemic of poisoning deaths have not been systematically evaluated. Promising strategies include stronger regulation to reduce the unsafe use of drugs, increased physician awareness, and support for best practices in treating drug dependence.

No. 949 Frequently Asked Questions

Q: How long is a prescription for a Schedule II drug valid?

A: A prescription is valid for one year from the date it is written. This is also true for Schedule V drugs.

Q: How would I decide if a Schedule II or Schedule V prescription is appropriate to fill when the date written is not "current"?

A: Use your professional judgment based on your knowledge of the specific situation. For example, you might question a Schedule II prescription written more than a week earlier if issued from an emergency room.

Q: How long are signed authorizations for non-child resistant containers (CRC) valid?

A: This question is not addressed in the Board regulation or by the Consumer Product Safety Commission. It does require each pharmacy to maintain a signature for each patient who requests non-CRCs. Each pharmacist must use professional judgment in regard to an appropriate time period. Visit *http://apps.leg.wa.gov/WAC/default.aspx?cite=246-869-230* for more information.

Q: What is the list of medical conditions for which a Schedule II stimulant can be prescribed?

A: Schedule II stimulants may be prescribed for the following conditions: multiple sclerosis; narcolepsy; hyperkinesis; drug induced brain dysfunction; epilepsy; differential diagnostic psychiatric evaluation of depression; treatment of depression which is refractory to other therapeutic modalities; or clinical investigation of such drugs.

Q. What information on a controlled substance prescription cannot be changed and requires a new prescription?

A. The pharmacist is never permitted to make changes to the patient's name, the controlled substance prescribed, or the prescriber's signature. These three changes require a new prescription. For additional questions and answers related to controlled substance prescriptions, please visit the federal Drug Enforcement Administration Web page at *www.deadiversion.usdoj.gov/faq/general.htm*.

Q: Can a prescription be filled or transferred from Puerto Rico or Guam?

A: Yes, a prescription from any US territory or insular possession can be dispensed by a Washington pharmacist. The prescription must be signed by a medical physician, osteopath, podiatrist, veterinarian, or dentist with an active license in his or her respective state.

Q: What licensed health care professionals have prescriptive authority limited to a specific list of medications, or formulary?

A: Naturopathic physicians and optometrists.

- ♦ Optometry drug list: *http://apps.leg.wa.gov/WAC/default.aspx?cite=246-851-580*
- ♦ Optometry guidelines for use of oral Schedule III through V controlled substances and legend drugs: *http://apps.leg.wa.gov/WAC/default.aspx?cite=246-851-590*
- ♦ Naturopathy drug list: *https://fortress.wa.gov/doh/hpqa1/hps7/naturopathy/documents/legendlist.pdf*

Q: What are the two basic conditions that must be satisfied to make a prescription valid?

A: The medication is for a legitimate medical purpose, and there is a patient-prescriber relationship.

Q: Can a responsible pharmacy manager for one pharmacy serve as a responsible pharmacy manager at another pharmacy?

A: Yes, a pharmacist can be a responsible pharmacy manager for more than one pharmacy.

No. 950 Fifty-year Certificates

Congratulations to the following pharmacists for 50 years of licensure in Washington State. Honorees were recognized at the Northwest Pharmacy Conference in June.

Michael J. Auer, Jr, Clarkston, WA; Richard H. Cedergren, Longview, WA; Edward L. Duhamel, Chelan, WA; Robert W. Higgins, Anacortes, WA; Burton K. Peterson, Seattle, WA; David Altaras, Bellevue, WA; Victor H. Grutchfield, Everett, WA; Amir H. Hemmat, Mercer Island, WA; Robert A. Mitchell, Sumas, WA; Tamio T. Miyata, Bellevue, WA; Ann Q. Rivenes, Livermore, CA; Elmer R. Rogers, Jr, Longview, WA; Ruth A. Vandever, Portland, OR; Raymond E. Cowman, Issaquah, WA; and Walter D. Gross, Bridgeport, WA.

No. 951 Welcome New Board Staff

We are pleased to announce that **Cathleen Williams** and **Tyler Varnum** have joined our staff. Cathy is a pharmacist consultant and will be working closely with the Board on special projects and rules. She has worked in retail pharmacy and state government. Cathy is a graduate of the University of Washington.

Tyler is the pharmacist inspector for the central region of the state. Tyler has worked in retail and hospital pharmacy settings. He is a graduate of Washington State University and has served in the United States Navy.

No. 952 Rule Development for Pharmacies in Correctional Facilities

The Board is considering rules to set minimum standards for pharmacies located in correctional facilities. The evaluation and standards for retail pharmacy settings are not always appropriate for the unique practice of pharmacy in these facilities. If you are interested in participating in this process or would like updates, please send the Board an e-mail at wsbop@doh.wa.gov to have your contact information added to the interested parties list.

The *Washington State Board of Pharmacy News* is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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